



October 10, 2002

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Docket management Branch  
HFA-305  
Food and Drug Administration  
Room 1061  
Rockville, MD 20852

Reference: Compliance Policy Guide Section 345.100 Male Condom Defects

Gentlemen:

Please accept this letter as comments to the above referenced Compliance Policy Guide Draft issued 3/29/02.

1. Air Burst Testing. The consensus standard accepted by the FDA is ISO 4074:2002. This standard was issued in February, 2002. It requires an AQL level for air burst of 1.5 not 1.0. Thus the guidance contained in the reference document calls for compliance at a higher level than the consensus standard cited. ASTM 3492-97 has always called for AQL 1.5. The FDA also recognizes this standard. A change to AQL 1.5 from 1.0 would be consistent with the position taken in Background 1 concerning the lowering of the water leak AQL to .25. The Sampling Plan Annex also needs to be changed to reflect the 1.5 AQL.
2. Definition of Lot. ISO 4074 is very specific about the definition of "lot". It states that a "lot" is "[a] collection of condoms of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed with the same lubricant and any other additive or dressing in the same type of individual container. ISO 4074 goes on to say that a "lot number" is "[a] number or combination of numerals, symbols or letters used by the manufacturer to identify a lot of individually packaged condoms, and from which it is possible to trace that lot through all stages of manufacture up to packaging." Therefore, the FDA should use the manufacturer's designation of a lot as the lot that is to be tested. The FDA should not build a composite lot based on condoms that shared the same container, but could random sample a container by choosing several lots as representative of the whole.
3. Test Method for Water Testing. Based on the ASTM study conducted, the laboratory method identified which is also the ISO method in 4074 should be supplemented with the Hang and Squeeze method.

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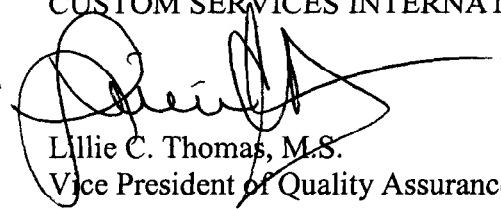
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4. Test Method for Air Burst. The ISO 4074 reference should be changed to properly reflect the standard. Air burst methodology is described in Annex G of ISO 4074:2002.

Thank you for your consideration of these comments

Sincerely,

CUSTOM SERVICES INTERNATIONAL INC.

A handwritten signature in black ink, appearing to read 'Lillie C. Thomas', is written over the printed name and title.

Lillie C. Thomas, M.S.

Vice President of Quality Assurance and Regulatory Compliance